

**REMARKS**

Upon entry of the present Reply, claims 1,-5, 7-12 and 14 are pending in this application. Claims 6 and 13 are cancelled herein, without prejudice.

**Objection to Specification**

The specification at page 3 has been amended to delete the sequence listing, and thereby to render moot the Examiner's objection to the inclusion of such sequence listing without including a sequence ID. Notice to such effect is respectfully requested.

**Objection to Claims**

Claims 1, 3, 7, 8 and 11 are amended herein to address the objections raised by the Examiner, and to delete language the Examiner contends to constitute an intended use and to not further limit the claims. Applicants respectfully submit that the foregoing amendments address and overcome the various claim objections. Notice to such effect is respectfully requested.

**Rejections of Claims over Ye et al.**

Claims 1-14 stand rejected as anticipated by Ye et al. Applicants respectfully traverse this rejection for at least the following reasons.

Ye et al. (Pharmaceutical Research, 19(9):1302-1309, September 2002) relates to evaluation of strategies for the intracellular delivery of proteins, and it uses luciferase reporter gene analysis in order to quantitatively evaluate strategies for intracellular delivery of biologically active proteins comprised of Gal4 DNA binding domain and VP16 trans-activation domain.

It is Applicants' understanding that in the Office Action, the disclosures in Ye et al. are contended to correspond to the claimed invention as follows. It appears that the Ye et al. disclosure "Gal4" is considered to correspond to "one or more homologous or heterologous binding proteins having DNA/RNA binding factor or DNA/RNA binding domain" in the present invention; that the disclosure of "Tat, VP22" among cell

penetrating peptide is considered to correspond to "PTD" in the present invention; that the disclosure of "Ga14 binding site" is considered to correspond to "a DNA/RNA binding sequence which is specifically bound to the DNA/RNA binding factor or DNA/RNA binding domain" in the present invention; and that the disclosure of the "luciferase reporter gene" is considered to correspond to "a biological regulatory molecule" in the present invention.

Applicants respectfully submit, however, that the present invention is distinctive from Ye et al. in at least the following points:

i) "A biological regulatory molecule" of the present invention is defined as a promoter or enhancer in itself that can express a gene in specific species, tissues, or cells (paragraph [0038] and claim 1). The "Luciferase reporter gene" disclosed in Ye et al. is completely different in that "A biological regulatory molecule" of the present invention comprises T cell specific Lck, CD2 promoter and pancreas-specific insulin promoter (paragraph [0030]), which actually carry out a regulatory function, whereas the luciferase is only a reporter.

ii) Ye et al. suggest HEK293 cells, i.e., only *in vitro* route, as a route for delivering various chimera proteins into cells, whereas step iv) in claim 7 and step v) in claim 8 of the present invention specify *in vivo* routes, including intramuscular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal or inhalation routes, which are supported by Examples 5 and 6 of the present invention.

For at least the foregoing reasons, Applicants respectfully submit that the presently pending claims fully distinguish over Ye et al. Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections of Applicants' claims over Ye et al.

#### **Rejections of Claims over Lee et al.**

Claims 1, 3-8 and 10-13 stand rejected as anticipated by Lee et al. (US7354737). In addition, claims 2, 9 and 14 stand rejected as obvious over Lee et al. in view of

Cartier et al. Applicants respectfully traverse this rejection for at least the following reasons.

**Statement of Common Ownership**

The present application and Lee, U.S. Patent No. 7,354,737 were, at the time the present invention was made, subject to an obligation of assignment to and/or were commonly owned by ForHumanTech Col., Ltd.

Applicants submit herewith a certified translation of the foreign priority application, thus removing Lee et al. as a reference. US 7354737 was granted in the name of the present applicant after being filed as a PCT application (W003/059940) and then entered into the US national phase. Since the PCT publication date of Lee et al. is July 24, 2003 and the priority date of the present invention is November 12, 2002, this reference is regarded as disqualified. As noted, Applicants have submitted herewith an English translation of priority document (Korean Patent Application No.1 02002-0070106).

With US 7354737 effectively removed as a reference, Applicants respectfully submit that Cartier et al., standing alone, is insufficient to have rendered obvious or otherwise unpatentable the presently claimed invention.

Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections of Applicants' claims based on US 7354737. The presently claimed invention is considered to patentably distinguish over Cartier et al., so that the rejections based on the combination of US 7354737 and Cartier et al. is rendered moot.

**Conclusion**

For the reasons set forth in the foregoing, Applicants respectfully submit that the present application is in condition for allowance, and an early notice to such effect is respectfully requested.

Should the Examiner consider that a telephone interview would be helpful to facilitate favorable prosecution of the above-identified application, the Examiner is invited to contact the undersigned at the telephone number provided below.

Petition and the fee for a one-month extension is submitted herewith. If any additional fees are required for the filing of this paper, Applicants request the Commissioner to charge the fees to deposit account #18-0988, dkt. no. NAMNP0103US.

Respectfully submitted,  
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